K012050

SEP - 6 2001

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Advanced Cardiovascular Systems, Inc.

Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95052

Telephone: 408/845-1067
Fax: 408/845-3743

Contact Person: Saba Modjarrad

Date Prepared: June 29, 2001

Device Trade Name: VIATRAC™ 14 PLUS Peripheral Dilatation Catheter

Device Common Name: Percutaneous Transluminal Angioplasty Catheter

Device Classification Name: LIT

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, and intended use features of VIATRAC™ PLUS Peripheral Dilatation Catheter are substantially equivalent with regard to these features in the predicate device, the RX VIATRAC™ 14 Peripheral Dilatation Catheter (K983055 and K000101).

Device Description:

The VIATRAC™ 14 PLUS Peripheral Dilatation Catheter is a rapid exchange catheter with an integrated shaft system and an XCELON™ (nylon blend) balloon bonded at the distal end. The shaft has a combination of a single lumen design at the proximal end and a coaxial lumen at the distal end. The proximal lumen provides for inflation of the balloon with contrast medium. The distal lumen permits use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal shaft has a tapered stainless steel mandrel, which provides support and flexibility to the shaft and is attached at the proximal end.

The balloon, which has 2 radiopaque markers to aid in positioning the balloon in the stenosis, is designed to provide an expandable segment of known diameter and length at specific pressures.

The proximal end of the catheter has a single arm adaptor that provides access to the inflation lumen. It is designed with a luer-lock fitting for connection with an inflation device.

The VIATRAC™ 14 PLUS Peripheral Dilatation Catheter is available with balloon diameters of 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0 mm, with lengths of 15, 20, 30, and 40 mm and in catheter lengths of 80 cm and 135 cm.

On the 135 cm catheter length, there are two proximal shaft markers (95 cm and 105 cm from the distal tip). On the 80 cm catheter length, there is a single proximal marker (55 cm from the distal tip). Both indicate the relative position of the catheter to the end of a brachial, femoral or renal guiding catheter. An additional marker is located at the guide wire exit notch and aids in locating the guide wire exit notch.

Intended Use:

The VIATRAC™ 14 PLUS Peripheral Dilatation Catheter is indicated for dilatation of stenoses in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices.

Performance Data:

The safety and effectiveness of the VIATRAC™ 14 PLUS Peripheral Dilatation Catheter has been demonstrated through data collected from *in vitro* bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Ms. Saba Modjarrad
Regulatory Affairs Coordinator
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054-2807

Re: K012050
Trade Name: VIATRAC™ 14 PLUS Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 10, 2001
Received: August 13, 2001

Dear Ms. Modjarrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application(PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

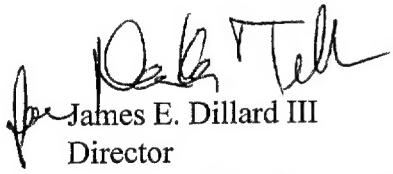
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21 CFR 1000-1050).

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K012050

Device Name VIATRAC™ 14 PLUS Peripheral Dilatation Catheter

Indications for Use The VIATRAC™ 14 PLUS Peripheral Dilatation Catheter is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012050